4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-2138]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0800. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910-0800--Extension

This information collection supports Agency implementation of the Drug Quality and Security Act (Pub. L. 113-54), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding new section 503B (21 U.S.C. 353b). Under section 503B(b) of the FD&C Act, a compounder can register as an outsourcing facility with FDA. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

Under section 503B(b)(5) of the FD&C Act, an outsourcing facility must submit adverse event reports to FDA in accordance with the content and format requirements established through guidance or regulation under § 310.305 (21 CFR 310.305) (or any successor regulations). Accordingly, we developed the document, "Guidance for Industry: Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." For a copy of guidance documents, go to

https://www.fda.gov/RegulatoryInformation/Guidances/default.htm, insert the title of the guidance document in the "Search" box and follow the prompts. The guidance explains electronic reporting of adverse events in accordance with § 310.305 with respect to outsourcing facilities.

Under § 310.305(c)(1), manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved NDA or ANDA, including, as set forth in the guidance, outsourcing facilities must submit to FDA adverse event reports within 15 calendar days of receiving the information and must submit follow-up reports within 15 calendar days of receipt of new information about the adverse event, or as requested by FDA. Outsourcing facilities must submit the adverse event report in an electronic format that FDA can process, review, and archive (collection of information is approved by OMB control number 0910-0291). A copy of the current labeling of the compounded drug product must be provided.

Under § 310.305(f), entities subject to the regulation must maintain for 10 years the records of all adverse events required to be reported under § 310.305. The outsourcing facility should also maintain records of its efforts to obtain the data elements described in the draft guidance for each adverse event report.

In the *Federal Register* of August 21, 2018 (83 FR 28854), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden for the information collection as follows:

Table 1.--Estimated Annual Reporting Burden[1]

Compounding Outsourcing Facility	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submission of adverse event reports including copy of labeling and other information as described in the guidance	55	1	55	1.1	61

Table 1.--Estimated Annual Reporting Burden[1]

Compounding Outsourcing Facility	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden[1]

Type of Recordkeeping	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records of adverse events, including records of efforts to obtain the data elements for each adverse event report	55	1	55	16	880

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This is the first extension of the information collection and we have retained the currently approved burden estimate. Based on our review of Agency data, we estimate that annually 55 outsourcing facilities ("Number of Respondents" and "Total Annual Responses" in table 1) will submit adverse event reports to FDA as specified in the guidance and that preparing and submitting this information will take approximately 1.1 hours per registrant ("Average Burden per Response" in table 1). Likewise, we estimate that annually 55 outsourcing facilities ("Number of Recordkeepers" in table 2) will maintain records of adverse events as specified in the guidance and that preparing and maintaining the records will take approximately 16 hours per registrant ("Average Burden per Recordkeeping" in table 2).

Dated: September 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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